Message

From: Tanner, Barbara [Tanner.Barbara@epa.gov]
Sent: 11/8/2018 6:00:51 PM
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Subject: News Articles (For EPA Distribution Only)

BNA DAILY ENVIRONMENT REPORT ARTICLES

Rep. Frank Pallone (D-N.J.) talks to reporters at the U.S. Capitol on Feb. 8, 2018 in Washington.
Photographer: by Chip Somodevilla/Getty Images

News

Democratic House Likely to Grill EPA on Chemicals Law

Posted Nov. 8, 2018, 9:08 AM

- Tonko plans TSCA oversight hearings if selected to chair subcommittee with jurisdiction
- Subpoena powers to uncover information about EPA's chemical decisions in Democrats' hands

Democrats will likely grill the Environmental Protection Agency next year on its implementation of the primary U.S. chemicals law.

Rep. Paul Tonko (D-N.Y.), will seek the chairmanship of the House Energy and Commerce's Environment Subcommittee, which has primary jurisdiction over the Toxic Substances Control Act, a committee aide told Bloomberg Environment Nov. 7.

If elected, Tonko plans to hold a TSCA oversight hearing early next year, the aide said.

"The effort to reform the law was a bipartisan achievement done in good faith. There is no reason that members on both sides of the aisle, environmental and public health groups, and the chemical industry should not want to ensure that the law is working as Congress intended," Tonko told Bloomberg Environment by email.

"Americans need a chemical safety program that works. Conducting oversight to understand if EPA is adequately protecting consumers, workers, and vulnerable populations—as required by the law—should be a top priority," he said.

Rep. Frank Pallone Jr. (D-N.J.), ranking member of the full committee, would like become its chairman, an aide for his office said Nov. 7. It is too early to say what Pallone's priorities would be, the aide said.

In his position as ranking member, Pallone repeatedly asked for TSCA oversight hearings, most recently during a Sept. 6 hearing on perfluorinated chemicals.

The breadth of companies affected by chemical policy includes major chemical manufacturers such as BASF Corp. and DowDuPont Inc. as well as automobile, aircraft, and information technology companies like Tesla Inc., Boeing Co., and the Intel Corp., all of which have weighed in on recent chemical regulations either directly or through trade groups.

Hearing Strategies

The new House will likely hold oversight hearings on many environmental issues, with a particular interest in TSCA, because that law was just overhauled in 2016, Stephen Owens, a partner with Squire Patton Boggs LLP's Phoenix office, told Bloomberg Environment.

Lawmakers "spent a lot of time working on it when the legislation was going through," said Owens, who testified before Congress about the chemicals law while serving as the EPA's assistant administrator for chemical safety and pollution prevention under President Obama. "They have a lot of sweat equity invested."

As the majority party, Democrats next year will enjoy powers they don't have for the remainder of this Congress, said Owens, who also served as counsel to a House Science and Technology oversight subcommittee in the early 1980s.

If the agency isn't responsive to initial requests, Democrats can now subpoena information, Owens said. If committees have reason to believe the agency hasn't fully disclosed information it should have, Democrats will be able to have EPA witnesses testify under oath, he said.

"Initially, they may try to be more collegial, but it wouldn't surprise me if they do that for some higher profile issues," Owens said.

Broader Support

Owens, Liz Hitchcock, acting director of Safer Chemicals Healthy Families, and Joanna Slaney, legislative director for health at the Environmental Defense Fund, said a wealth of chemical issues could be fodder for hearings.

Any of the issues environmental groups have teed up in their lawsuits challenging three agency rules could be subjects, Owens said.

Those lawsuits challenge the EPA's approach to selecting chemicals for risk assessment, its conduct of those risk analyses, and its alleged failure to ensure that the public has as much access to chemical information as the law requires.

The American Chemistry Council, which represents most of the U.S. chemical manufacturing industry, also welcomes oversight hearings, it said in a statement provided to Bloomberg Environment.

"Congress should continue to exercise its oversight responsibilities to help ensure the law is being implemented as intended," the chemistry council said.

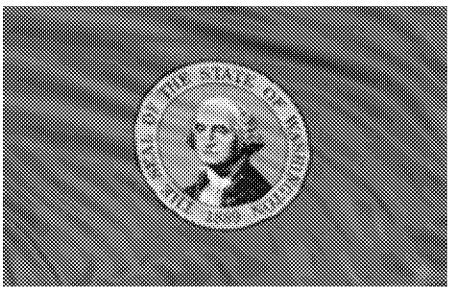
https://news.bloombergenvironment.com/environment-and-energy/democratic-house-likely-to-grill-epa-on-chemicals-law

CHEMICAL WATCH ARTICLES

Washington state weighs policy options on flame retardants

Final report to legislature expected next July

7 November 2018 / Built environment, Children's products, Halocarbons, United States



Washington state officials are to meet with flame retardant stakeholders this week, the latest step by the Department of Ecology (ECY) and Department of Health (DOH) in their ongoing effort to address the substances and to consider a more preventative approach.

A 2016 law banned five flame retardants from children's products and directed the state to act on six others:

- IPTPP (isopropylated triphenyl phosphate);
- TBB ([2-ethylhexyl]-2,3,4,5- tetrabromobenzoate);
- TBPH (bis [2-ethylhexyl]-2,3,4,5- tetrabromophthalate);
- TCPP (tris [1-chloro-2-propyl] phosphate);
- TPP (triphenyl phosphate); and
- V6 (bis[chloromethyl] propane-1,3-diyltetrakis [2-chloroethyl] bisphosphate).

As a consequence, officials are seeking input about potential policy options and considering presentations on fire safety.

The timeline for these discussions has been extended to balance other "priority" DOH work. Officials now expect to post a draft report with findings, policy options and recommendations for stakeholder review and comment by April 2019, with a final report for the legislature by July that year.

Washington is not the first US state to restrict the use of certain flame retardants in products. California, Minnesota and Washington, DC have made similar moves but the state was the first to restrict the use of TBBPA, according to NGO, Washington Toxics Coalition.

Issues under consideration

The November stakeholder meeting at the DOH offices in Tumwater, southwest of Seattle, will follow others in June and September.

The DOH, ECY and stakeholders considered grouping chemicals for easier safety assessments, at the most recent.

"Cumulative impacts seem so critical, and working one chemical at a time doesn't seem efficient," Laurie Valeriano, executive director of Toxic-Free Future, said, according to draft meeting notes.

"Grouping chemicals should be included in the conversation. The rational approach is to look more broadly at a group of chemicals instead of individual chemicals," she added.

But Steve Scherrer, of Lanxess Solutions – which develops, manufactures and markets engineered industrial specialty chemicals – disagreed.

Reviewing chemicals one-by-one has "some advantages since they are regulated individually and made by different companies," he said. Grouping chemicals together would not be a "scientific approach", he added.

The group also discussed safer alternatives assessments and different flame retardant regulations in various markets. And the ECY and DOH presented toxicity information on the substances under review and identified certain data gaps.

The upcoming meeting will see a shift in focus to flame retardant usage in certain products, including building insulation, residential furniture and juvenile products, according to an agenda.

Lisa Martine Jenkins
Americas reporter

Related Articles

- Washington state seeks 'prevention approach' on flame retardants
- Washington governor signs flame retardant ban into law

Further Information:

- Committee information and meeting materials
- November meeting agenda

Canada-US regulatory cooperation consultation extended

8 November 2018 / Canada, United States

The US Office of Information and Regulatory Affairs (OIRA) has extended its consultation on how the federal government can reduce or eliminate unnecessary regulatory differences between the US and Canada.
Comments on the request for information (RFI) will now be accepted until 10 December, according to an email sent to stakeholders by the US Department of Commerce's International Trade Administration.

The effort to reduce regulatory divergences comes under the two countries' Regulatory Cooperation Council (RCC), which was established in 2011.

The next RCC stakeholder event is scheduled for 4-5 December in Washington, DC.

Related Articles

- US department calls for comments on regulatory cooperation with Canada

Further Information:

- RFI notice

US NGOs press for extended consultations on TSCA risk evaluations

8 November 2018 / TSCA, United States

Four NGOs are pressing the US EPA to take the maximum time permitted under TSCA for completing its first ten risk evaluations under the reformed law.

The request came in a 30 August letter in which the organisations cautioned EPA Acting Administrator Andrew Wheeler that the risk evaluations will "fall short under TSCA and seriously damage EPA's credibility if they are not based on the best available science".

The groups are urging the EPA to allow 120 days for comments on the draft evaluations, which are set to be released in late 2018 or early 2019. And they say that EPA should take advantage of its statutory authority to extend its three year completion deadline by an additional six months, which would mean finalising the evaluations by 30 June 2020.

Such an extension, they say, "would provide additional breathing space for the public comment and peer review process, increasing the likelihood that EPA receives high-quality comments and giving the reviewers the time necessary for an in-depth examination of draft evaluations and preparation of detailed reports".

The letter also makes several recommendations around the peer review process, including around grouping the review of substances with common issues, offering opportunities for the public to weigh in, and the need for conflicts of interest and bias analysis for potential reviewers.

The letter was co-signed by:

- Safer Chemicals Healthy Families;
- Environmental Health Strategy Center;
- Natural Resources Defense Council; and
- Earthjustice.

The organisations are among several in the consumer advocacy community that have raised concern over the narrowed scope of the EPA's reviews, as detailed in the substances' problem formulation documents.
Note: Your access to this subscriber-only article is through a corporate subscription

Related Articles

- EPA names first ten chemicals for new TSCA evaluations
- EPA 'narrowing' scope of first ten TSCA risk evaluations
- EPA issues TSCA 'problem formulation' documents

Further Information:

- Letter

US FDA proposes cosmetics allergens consumer survey

8 November 2018 / Data, Personal care, United States

The US Food and Drug Administration (FDA) is seeking public comment on a proposed consumer survey about allergens in cosmetics.

This is the first survey on consumer perceptions of cosmetics the FDA has conducted since 1975.

The purpose of the survey is to collect information to improve the FDA's understanding of adverse events caused by allergens in cosmetics, according to a notice in the *Federal Register*.

The agency also hopes to better grasp "consumer perceptions and awareness as well as consumer behavior regarding allergens in cosmetics". This includes decisions to purchase specific products or to avoid certain ingredients, when to contact a health care provider, and when to report an adverse event.

"Gathering information about consumer experiences with cosmetic products, especially adverse reactions such as irritated skin or an allergic reaction, is critical to the FDA's ability to effectively conduct surveillance and oversight of these products," said Scott Gottlieb, the agency's commissioner.

The information is "an important step in advancing a process for reducing exposure to allergens in vulnerable individuals", he added.

In order to move the survey forward, the FDA must receive approval from the White House's Office of Management and Budget (OMB). The first step in that process is to hold a public consultation.

Comments will "help ensure we are collecting all relevant information", added Dr Gottlieb. The agency will be accepting these for 60 days.

If the FDA obtains OMB's permission, it plans to begin conducting the survey in 2019.

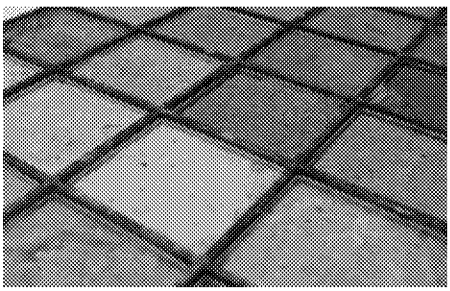
Further Information:

- FDA release
- Federal Register notice (pre-publication)

Canada links cosmetics colourant to cancer risk

Industry says not all data accounted for however

8 November 2018 / Canada, Environmental Protection Act, Risk assessment



Solvent violet 13, a colourant found in a wide range of consumer products including cosmetics and toys, is harmful to human health at current levels of exposure, according to a draft conclusion from the Canadian government.

If confirmed, the conclusion would most likely trigger risk management measures against the substance. However, industry says that the assessment does not take into account the most recent toxicity data available in the solvent violet 13 REACH registration dossier.

The government published a draft screening assessment of seven anthraquinone substances on 3 November. The substances are used as colourants in: cosmetics, food packaging materials, children's arts and crafts materials, toys, do-it-yourself products, and textiles.

The seven substances were originally part of a group of 15 anthraquinones prioritised under the Chemicals Management Plan. The government previously assessed eight of the 15 and found that they were of low concern.

The remaining seven are:

- solvent violet 13;
- pigment blue 60;
- solvent violet 59;
- solvent blue 36;
- disperse red 60;
- acid blue 239; and
- "9,10-Anthracenedione, 1,4-diamino-, N,N'-mixed 2-ethylhexyl", including methyl- and pentyl- derivatives.

The draft screening assessment of these substances used read-across for the human health hazards owing to a scarcity of health effects data.

It found a potential to cause carcinogenicity for all apart from pigment blue 60 and potential to cause adverse developmental effects for solvent violet 13 and solvent blue 36.

Using carcinogenicity as the critical effect, the assessment concluded that pigment blue 60 meets one of the criteria in section 64 of the Canadian Environmental Protection Act (Cepa).

The assessment used the "ecological risk classification of organic substances" approach to predicting the environmental risks, which was published in 2016 by Environment and Climate Change Canada. This led to the conclusion that all seven substances represented low risk of harm to the environment.

Industry response

However, Dr Pierfrancesco Fois, deputy executive director at colourants trade association Etad, says that some of the data gaps identified in the assessment can be filled, reducing uncertainty in the risk characterisation.

For example, the assessment suggests that for solvent violet 13 there are no studies covering:

- *in vivo* genotoxicity;
- developmental or reproductive toxicity; or
- repeated-dose or chronic animal studies for oral exposure.

However, Dr Fois says that the solvent violet 13 REACH registration dossier contains data for:

  - an *in vivo* micronucleus test showing no mutagenicity;
  - a reproductive toxicity test via oral route; and
  - a repeated dose toxicity test, via oral route.

"Similar additional information exists for other substances in the list," he says. "If we can eliminate, or at least minimise, these sources of uncertainty, we will have an assessment which reflects better the properties of the single substances ... Until this process is completed, it is too early for drawing any conclusion on the risk of solvent violet 13."

The government has started a 60-day public consultation, which closes on 2 January.

Andrew Turley
Science editor, Chemical Watch

Further Information:

- Draft screening assessment
- Canada Gazette notice
- Science approach document for the ecological risk classification of organic substances
- Brief profile for solvent violet 13 REACH registration dossier

EPA pressed to use 'discretionary' TSCA authority to address PFASs

8 November 2018 / PFCs, TSCA, United States

Members of the consumer advocacy community are urging the US EPA to use its discretionary authority under TSCA to address what some describe as a 'PFAS crisis', attendees at the Chemical Watch US Regulatory Summit have heard. Recent months have seen unprecedented focus on perfluoroalkyl and polyfluoroalkyl substances (PFASs), amid concern over the substances' potential health impacts and their widespread prevalence in humans and the environment. The EPA has responded to these concerns by launching a PFAS action plan and holding community engagement events across the country.
But while most of the agency's efforts have focused on developing drinking water limits or cleaning up legacy substances, Eve Gartner, an attorney with the environmental law nonprofit Earthjustice, said that there is an "important opportunity to see if TSCA can be an effective tool in the process".

Much of the focus on TSCA has been on how the EPA implements the mandated amendments to the law, Ms Gartner told delegates at the Arlington, Virginia meeting, while speaking on a panel of stakeholders about the reformed law. But, she said that it is "critically important to look at how EPA is using its discretionary TSCA authority to address emergent situations involving potentially toxic substances".

For example, Ms Gartner suggested that the agency uses its Section 4 authorities to require additional testing, to "ensure that the public and other regulators have more information on the specific PFAS chemicals that are being identified in drinking water but for which we now have few or no health studies".

She also asked whether the EPA would commit to requiring that all new PFASs be subject to a full pre-manufacture notice (PMN) review, and not be allowed to come to market through a Section 5 exemption, such as a research and development or test-market exemption (TME).

And she pressed the agency to "close the door" on the use of long-chain chemistries that have been largely abandoned domestically, by blocking the import of "all articles, including recycled articles coming into this country, that contain PFOA or PFOS".

The US EPA told Chemical Watch that it conducts full assessments of chemicals submitted under exemption applications to determine whether the chemicals will present an unreasonable risk of injury to human health and the environment. The assessment process is the same as that used to evaluate PMNs and significant new use notices (Snuns), it added, with the distinction that the substances must be manufactured in accordance with the exemption's parameters and with the specific uses, controls and site locations described in the exemption notice.

The agency has also acted to address articles containing PFASs through the use of significant new use rules (Snurs). In 2013, it finalised a Snur that requires notice and review before manufacturers (including importers) of carpets treated with certain PFAS chemicals could commence those activities.

In 2015, the EPA proposed a Snur for PFOA and PFOA-related chemicals, including as part of articles, but that rule has not yet been finalised.

Related Articles

- US Senate subcommittee holds hearing on PFAS 'crisis'
- US environmental groups lobby Congress for ban on new PFASs
- Pruitt pledges EPA action on legacy PFASs
- EPA lays out TSCA implementation priorities
- US EPA issues Snur to restrict import of perfluorinated chemicals
- US EPA proposes Snur for perfluoroalkyl carboxylates

Further Information:

- EPA action on PFASs

US EPA round-up

8 November 2018 / TSCA, United States

EPA watchdog to evaluate agency's risk assessment processes

The Office of Inspector General (OIG) for the US EPA is conducting "preliminary research" into the agency's risk assessment process, to determine whether the EPA is following federal criteria.

Among the projects for which the watchdog is seeking associated "documented risk assessments" is the EPA's work on endocrine disruptors. It has been asked to furnish these documents by 30 November.

Agency pressed for extended consultation on TSCA prioritisation approach

NGO the Environmental Defense Fund has requested that the EPA extend the public comment period on itsdraft approach for prioritising chemicals for risk evaluation under TSCA.

The document, *A working approach for identifying potential candidate chemicals for prioritisation*, was officially published on 5 October with a 15 November comment deadline. The EDF has asked this be extended by 32 days, to 17 December.

Committees to discuss PFAS recommendations

The EPA's Small Communities Advisory Subcommittee (SCAS) and the Local Government Advisory Committee (LGAC) will convene via teleconference on 14 November to discuss recommendations regarding per- and polyfluoroalkyl substances (PFASs) and their impacts on small communities, in view of water regulations.

Both will be open meetings and include an opportunity for public comment.

Nominees sought for lead model software review panel

The Science Advisory Board (SAB) is seeking scientific experts to form a panel to review the EPA's draft All-Ages Lead Model (AALM) software and model documents.

The AALM is "a tool for rapidly evaluating the impact of possible sources of lead on blood and other tissue levels in humans from birth to 90 years of age." It is used to predict lead concentrations in body tissues and organs.

Nominations will be accepted until 23 November.

Related Articles

- EPA outlines approach for identifying TSCA prioritisation candidates
- US EPA round-up

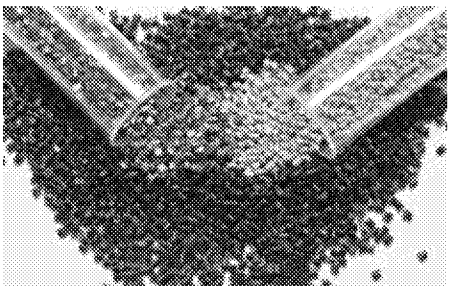
Further Information:

- EPA OIG project notice
- SCAS and LGAC meetings
- Lead model software nominations

'Moderate evidence' linking DINP to male reproductive effects

EPA-led systematic review

8 November 2018 / Food & drink, Food contact, Phthalates, Risk assessment, Sweden, United States



There is "moderate evidence" that the phthalate DINP may cause male reproductive effects at levels seen in human populations, according to a systematic literature review led by the US Environmental Protection Agency (EPA).

DINP is widely used as a replacement for DEHP, which is a substance of very high concern (SVHC) under REACH.

The review team was led by Elizabeth Radke from the EPA and included researchers from Brown University and the University of Michigan. They focused on six phthalates: DEHP, DINP, DBP, DIBP, BBP and DEP.

Despite some "inconsistencies", they found "robust evidence" of an association between exposure to DEHP or DBP and male reproductive outcomes. For DINP and BBP the equivalent evidence was "moderate", and for DIBP and DEP "slight".

The team suggest that the differing evidence levels may result from the fact that DEHP and DBP had the largest number of studies in the review. "While it is possible there are differences in potency or activity" for the pairs of phthalates, the researchers suspect that the review's "inadequate sensitivity" for DINP, BBP and DIBP may explain the results.

"It would be inappropriate to conclude that substituting DINP for DEHP or DIBP for DBP would be health protective," they write in *Environment International*.

For DINP, evidence of an association between exposure and male reproductive outcomes was based primarily on studies of testosterone and semen parameters. For DEHP, evidence came from data on anogenital distance, semen, and testosterone.

The review team plans a 2019 editorial looking at issues that apply to all phthalate studies, such as correlations across phthalates.

DINP increasingly detected

Meanwhile, in a technical report in *Pediatrics*, a team led by Leonardo Trasande from New York University, US, has drawn attention to DEHP's replacement by DIDP and DINP, which it says are "increasingly detected within the population".

The researchers highlight data from the US National Health and Nutrition Examination Survey (Nhanes), which indicate that DIDP and DINP have been detected in 94% and 98% of the population, respectively. They suggest that the chemicals are widely identified as food contaminants and cite cross-sectional Nhanes data correlating their metabolites with insulin resistance.

In a blog response, the American Chemistry Council (ACC) has pointed out that "general purpose" plasticisers such as DINP are "only cleared for a narrow range of food contact applications, specifically at temperatures not exceeding room temperature". Such plasticisers are "unlikely" to be present in microwaveable food contact articles, it adds.

The blog points out that DINP and DIDP are "two of the most studied phthalates and have been evaluated by multiple regulatory agencies over the past 20 years". Regulatory agencies "continue to affirm that DINP and DIDP are safe in all current applications and do not pose a dietary concern to the general public via exposure in food packaging", it concludes.

In March 2018, Echa's Risk Assessment Committee (Rac) rejected Denmark's proposal to classify DINP as a category 1B reproductive toxicant.

Speech delay from banned phthalates

Compounding the concerns about phthalates, independent studies of 1333 mother–child pairs suggest that exposure to certain phthalates during the first trimester of pregnancy is "significantly" associated with language delay in pre-school children.

The results come from the Swedish Environmental Longitudinal Mother and Child, Asthma and Allergy (SELMA) study conducted in prenatal clinics throughout Värmland county in Sweden and the Infant Development and the Environment Study (TIDES) conducted in the US.

Researchers measured urinary levels of the phthalates DBP and BBP during pregnancy. When the children reached the age of three, parents answered questionnaires on word comprehension.

The researchers, who were led by Carl-Gustaf Bornehag from Karlstad University in Sweden, were "surprised" to find that the results from the two countries were very similar.

Like DEHP, DBP and BBP are SVHCs under REACH and require authorisation before use. The European Commission is amending the authorisation list entries to cover endocrine disrupting properties with effects on human health, as well as reproductive effects.

Dr Emma Davies
Reporter

Related Articles

- Industry slams CLH proposal for DINP
- No classification for DINP, Echa committee decides

Further Information:

- EPA systematic review (abstract)
- Trasande et al technical report (full text)
- ACC blog
- Prenatal phthalate exposure and language development (abstract)

Canada clears 72 substances, proposes Snacs on 2 others

8 November 2018 / Canada, Environmental Protection Act

The Canadian government has concluded that 72 substances do not pose a threat to human health or the environment, according to a final screening assessment. It has also moved to impose significant new activity (Snac) provisions on two additional substances assessed in the grouping.

The final determination follows a draft assessment issued in June 2017. The substances were grouped together after the government conducted two large-scale risk assessments on hundreds of substances, one covering human health and the other addressing ecological concerns.

The 74 substances addressed in the recently finalised assessment represent the subset meeting 'low hazard' criteria in both of the broader assessments.

The final assessment upholds the draft conclusion that 72 of the substances do not meet section 64 criteria of the Canadian Environmental Protection Act, 1999 (Cepa). The government is therefore proposing no further action on these.

The remaining two substances – ethane, 1,1'-oxybis[2-methoxy- (diglyme) and 2,5,8,11-tetraoxadodecane (triglyme) – are considered to have human health effects of concern. The government says there are suspicions that new activities that have not been identified or assessed could lead to their meeting Cepa toxicity criteria.

Consequently, it intends to apply Snac provisions to both substances to require government notification before any such new uses are undertaken.

There is a 60-day comment period on the proposed Snacs.

Related Articles

- Canada provisionally clears 162 substances in draft assessments

Further Information:

- Final screening assessment
- Background on substances

EU publishes revised guidance on cosmetic ingredients testing

8 November 2018 / Cosmetic products Regulation, Europe, Personal care, Test/non test methods

The European Commission's Scientific Committee on Consumer Safety (SCCS) has published a revision of its guidance notes to provide assistance with testing and safety evaluation of cosmetic ingredients in the EU.

The tenth version of the notes, adopted after the SCCS' plenary meeting on 24-25 October, includes:

- an update on non-animal toxicological studies for cosmetic ingredients;
- a toolbox for further evaluation in a weight of evidence (WoE) approach for mutagenicity and genotoxicity;
- an update of criteria for multi-constituent natural ingredients and chemical identity; and
- a literature overview of consumer exposure data in Appendix 7.

The threshold of toxicological concern concept (TTC) has not been changed.

The guidance notes should not be seen as a prescriptive procedure, the SCCS said. Instead they outline an approach that may have to be adapted on a case-by-case basis.

However, it added, in case of major deviations from safety evaluation process protocols and procedures, applicants must provide scientific justification.

The SCCS notes will be revised in order to incorporate the progress of scientific developments or legislative changes.

In related news, the European Commission's DG Grow has requested the SCCS to deliver opinions on some cosmetic ingredients by February 2019.

Related Articles

- EU requests Opinions on number of cosmetic ingredients

Further Information:

- SCCS guidance notes

Echa round-up

8 November 2018 / Accidents, emergency response & poison centres, Classification, labelling and packaging Regulation, Europe, REACH

Advice on updating REACH dossiers

Echa has released advice on keeping registrations up to date, including a guidance document and an animation to help with the obligation. It is a legal requirement to update dossiers with new information so they need regular review, the agency says.

Reasons for updating a dossier include:

- change in production or import;
- new data on properties;
- different measures for safe use; and
- contact details change.

Registrants still need to find ways to collect information following successful registration and agree with co-registrants on how to make best use of it, the agency says.

REACH evaluation recommendations

The agency has published a number of recommendations based on its findings from REACH evaluation. These cover the topics: general recommendations; registration; substance identification; substance information requirements; adaptations; exposure assessment and risk characterisation; decision under dossier and substance evaluation; and regulatory risk management.

Registrants need to proactively update and review information in order to improve dossier quality, it says.

As part of the agency's update to its public activities coordination tool (PACT), there is now a single table to check which substances are under evaluation and follow their progress.

Testing proposals

Echa is inviting scientifically valid information and studies for the following substances and hazard endpoints:

- **1-dodecene, dimers**: reproductive toxicity (prenatal developmental toxicity);
-
  - **2,2,4,4,6,8,8-heptamethylnonane**: reproductive toxicity (extended one-generation reproductive toxicity study). Note: testing proposed with two substances in a grouping approach: icosane and hydrocarbons, C14-C19, iso-alkanes, cyclics; aromatics <2%;
  - **alkane-alpha,omega-diyl bis{[(trimethoxysilyl)propyl]carbamate}_M2**: reproductive toxicity (prenatal developmental toxicity). Note: testing proposed with methyl [3-(trimethoxysilyl) propyl]carbamate;
  - **alkenes, C13-14, hydroformylation products, distn. residues**: reproductive toxicity (extended one-generation reproductive toxicity study). Note: testing proposed with alkenes, C11-12, hydroformylation products, distn. residues;
  - **alkenes, C7-9, hydroformylation products, distn. residues, heavy cracked fraction**: reproductive toxicity (extended one-generation reproductive toxicity study);
  - **diethyl ether**: reproductive toxicity (extended one-generation reproductive toxicity study);
  - **fatty acids, C12-14, α-sulfo, disodium salts**: reproductive toxicity (prenatal developmental toxicity) and sub-chronic toxicity (90-day): oral;
  - **hydrocarbons, C14-C16, n-alkanes, <2% aromatics**: reproductive toxicity (extended one-generation reproductive toxicity study); and
  - **hydrocarbons, C14-C17, n-alkanes, <2% aromatics**: reproductive toxicity (extended one-generation reproductive toxicity study). Note: testing proposed with two substances in a group: icosane and hydrocarbons, C14-C19, isoalkanes, cyclics, < 2% aromatics.

The deadline for submitting information is 12 December.

Webinar on notifying poison centres

Echa is running an online information session to help with the process of notifying hazardous substances to poison centres. There will be a step-by-step explanation and opportunity to pose questions to a panel of experts.

It will take place on 11 December, 11.00-12.00 EET.

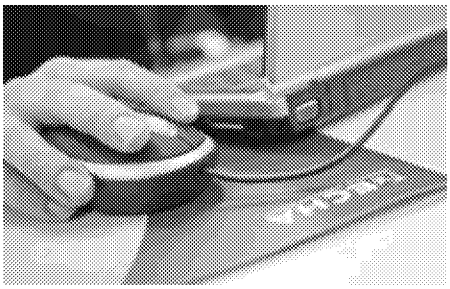
Further Information:

- Animation on REACH dossier updates
- Guidance on REACH registration
- Recommendations to REACH registrants
- Current testing proposals
- Poison centres webinar

Echa plans increased scrutiny of REACH dossier 'opt-outs'

Decision follows BoA call for 'thorough' checks

8 November 2018 / Data, Europe, REACH



Echa will manually check all new REACH registrations with 'opt-outs' from joint data submissions from 1 December, as part of efforts to increase scrutiny of such dossiers for completeness and compliance.

Under the regulation, companies choosing to opt out of data submitted jointly with co-registrants are required to provide "a proper justification" for the substance registration to be considered complete.

This is to see if companies provide a "justifiable reason" in cases where they want to submit their own data or when they have a dispute about access to data.

But a decision by Echa's Board of Appeal (BoA) in March concerning a dispute over a joint registration for charcoal prompted Echa to start inspecting opt-out justifications manually, a spokesperson told Chemical Watch.

In the charcoal case, the BoA concluded that if a registrant decides to rely on a 'complete opt-out' and informs Echa and the lead registrant accordingly, the registrant cannot be prevented from making its separate submission part of the joint dossier and Echa must grant it access to the joint registration.

A complete opt-out requires "heightened scrutiny", the BoA said, and Echa must "conduct a thorough completeness check of opt-out dossiers and prioritise them for a compliance check".

'Token'

Following the BoA recommendation, Echa changed its procedures on 17 May, providing a 'token' to access the joint submission to all registrants with full opt-outs and manually checking their justifications. Dossiers with full opt-outs are subject to the same level of completeness as the lead registrant dossier, Echa said.

From December however, the agency will manually check all new registrations with opt-out information, whether they are for a complete or partial opt-out. It estimates one percent of new registrations will have an opt-out.

The move follows a major revamp of REACH dossier compliance processes to improve data quality, announced by Echa in September. From January, it will send draft evaluation decisions to all registrants of a non-compliant dossier, not just the lead registrants.

Manual checks

To help registrants provide complete opt-out justifications for manual checks, Echa has developed templates in the latest version of Iuclid 6 software.

Registrants are advised to run the 'validation assistant' on their data before submitting their dossiers, the agency said.

If a justification is not complete, the registrant will fail the completeness check and will be given a deadline for providing the missing information. If it fails to do that, Echa added, the registration will be rejected.

Earlier results

Of 91,536 REACH registrations Echa has received so far, those with opt-outs have totalled 853, representing just less than one percent. Echa has manually checked 71 opt-outs since May.

In the majority of the cases – 61 so far – the opt-out justification has been that it is "disproportionately costly to submit the information jointly". The second most common reason has been "disagreement on the selection of the information", stated in 10 dossiers.

There have been no justifications based on "disclosure of commercially sensitive information likely to cause substantial commercial detriment".

Clelia Oziel
EMEA correspondent

Related Articles

- Major revamp of REACH dossier compliance processes announced
- Data disputes leave 160 REACH registrations pending
- Ueapme pushes for more 'workable' REACH for SMEs

Further Information:

- Echa manual verification
- BoA decision

OTHER ARTICLES

Washington state weighs policy options on flame retardants

Chemical Watch

"Cumulative impacts seem so critical, and working one **chemical** at a time doesn't seem efficient," Laurie Valeriano, executive director of **Toxic**-Free ...